



10/25/04

ATTORNEY DOCKET NO.: 2002834-0232 (Bacterial Delivery DIV2)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Caplan Examiner: Huynh
Serial No.: 10/728,323 Art Unit: 1644
Filing Date: December 4, 2003
Title: MICROBIAL DELIVERY SYSTEM

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

TRANSMITTAL LETTER

Enclosed are the following documents:

1. Form PTO-1449 (10 pages);
2. Supplemental Information Disclosure Statement (5 pages);
3. Transmittal Letter (1 page);
4. Limited Recognition Under 37 CFR § 10.9(b); and
5. Return Postcard.

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,

Charles E. Lyon, D.Phil
Agent for Applicant
Limited Recognition Under 37 CFR §10.9(b)

Choate, Hall & Stewart
Exchange Place
53 State Street
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(617) 248-5000

Dated: 10/22/04

Certificate of Mailing

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Sandra Saccoccia

Typed or Printed Name of person signing certificate



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Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 CFR §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

An *original* Information Disclosure Statement; or
 A *supplemental* Information Disclosure Statement.

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10/22/04
Date

Sandra Saccoccia
Signature

Sandra Saccoccia
Name of Person Signing

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

[X] Pursuant to 37 CFR § 1.97(b); no fee or certification is required:

[] Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);

[] Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;

[X] Before the mailing of a first Office action on the merits; or

[] Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.

[] Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:

[] Certifies that *either*:

[] each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

[] That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual

designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; or

- [] Includes herewith the fee set forth in § 1.17(p),
- [] Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:
 - [] Certifies that *either*:
 - [] each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - [] That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; and
 - [] Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

[] A copy of each cited reference not indicated with an asterisk is included;

[X] Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status
09/731,375	December 6, 2000	Published

[] Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

[X] Does not contain non-English language citations;

[] Includes one or more translations of a non-English citation; or

[] Does contain non-English language citations, of which the following is a concise explanation:

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC §102.

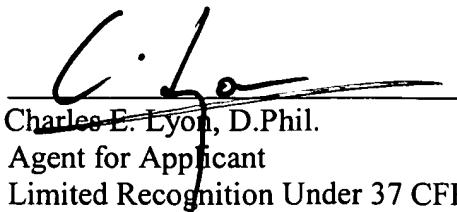
It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

Dated: 10/22/04



Charles E. Lyon, D.Phil.
Agent for Applicant
Limited Recognition Under 37 CFR §10.9(b)

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PTO-1449
(REV. 8-83)



U.S. Department of
Commerce
Patent and Trademark Office

ATTY. DOCKET:
2002834-0232

IN RE
APPLICATION NO.:
10/728,323

APPLICANT: Caplan

FILING DATE:
December 4, 2003

GROUP: 1644

**SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT**
(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass

U.S. PATENT APPLICATIONS

Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:

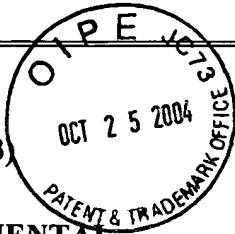
FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	Date	Translation	
				Yes	No

OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	*Amorim, et al., "Suppression of Airway Eosinophilia by Killed Mycobacterium Vaccae-Induced Allergen-Specific Regulatory T-Cells", <i>Nature Medicine</i> , 8(6): 625-629, 2002.
	*Asturias, et al., "Is Tropomyosin an Allergen in Anisakis?", <i>Allergy</i> , 55: 898-890, 2000.
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PTO-1449
(REV. 8-83)



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	*Barnes, P.J., "IL-10: A Key Regulator of Allergic Disease", <i>Clinical and Experimental Allergy</i> , 31 : 667-669, 2001.
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<p>*Diaz-Perales, et al., "Lipid-Transfer Proteins as Potential Plant Panallergens: Cross-Reactivity Among Proteins of Artemisia Pollen, Castanea Nut and Rosaceae Fruits, with Different IgE-Binding Capacities", <i>Clinical and Experimental Allergy</i>, 30: 1403-1410, 2000.</p> <p>*Diaz-Perales, et al., "Characterization of Asparagus Allergens: A Relevant Role of Lipid Transfer Proteins", <i>J. Allergy Clin. Immunol.</i> 110: 790-796, 2002.</p> <p>*Dorion, et al., "The Production of Interferon-γ in Response to a Major Peanut Allergy, Ara h II, Correlates with Serum Levels of IgE Anti-Ara h II", <i>J. Allergy Clin. Immunol.</i> 93: 93-99, 1994.</p> <p>*Durham, et al., "Immunologic Changes Associated with Allergen Immunotherapy", <i>The Journal of Allergy and Clinical Immunology</i>, 102(2): 157-164, 1998.</p> <p>*Erb, et al., "Atopic Disorders: A Default Pathway in the Absence of Infection?", <i>Immunol. Today</i>, 20: 317-322, 1999.</p> <p>*Eriksson, et al., "Cloning and Characterisation of a Group II Allergen from the Dust Mite Tyrophagus Putrescentiae", <i>Eur. J. Biochem.</i> 251: 443-447, 1998.</p> <p>*Eriksson, et al., "Cloning of Three New Allergens from the Dust Mite Lepidoglyphus Destructor Using Phage Surface Display Technology", <i>Eur. J. Biochem.</i> 268: 287-294, 2001.</p> <p>*Fahlbusch, et al., "Purification and Partial Characterization of the Major Allergen, Cav p 1, from Guinea Pig Cavia Porcellus", <i>Allergy</i>, 57: 417-422, 2002.</p> <p>*Fiorentino, et al., "Two Types of Mouse T Helper Cell", <i>J. Exp. Med.</i> 170: 2081-2095, 1989.</p> <p>*Francis, et al., "Induction of IL-10$^+$CD4$^+$CD25$^+$ T Cells by Grass Pollen Immunotherapy", <i>J. Allergy Clin. Immunol.</i> 111: 1255-1261, 2003.</p> <p>*Gafvelin, et al., "Cross-Reactivity Studies of a New Group 2 Allergen from the Dust Mite Glycyphagus Domesticus, Gly d 2, and Group 2 Allergens from Dermatophagoides Pteronyssinus, Lepidoglyphus Destructor, and Tyrophagus Putrescentiae with Recombinant Allergens", <i>J. Allergy Clin. Immunol.</i> 107: 511-518, 2001.</p> <p>*Giuliani, et al., "Isolation and Purification of a Major Allergen from Parietaria Officinalis Pollen", <i>Allergy</i>, 42: 434-440, 1987.</p>			

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<p>*Kalliomaki, et al., "Transforming Growth Factor-β in Breast Milk: A Potential Regular of Atopic Disease at an Early Age", <i>J. Allergy Clin. Immunol.</i> 104(6): 1251-1257, 1999.</p> <p>*Kleine-Tebbe, et al., "Severe Oral Allergy Syndrome and Anaphylactic Reactions Caused by a Bet v 1-Related PR-10 Protein in Soybean, SAM22", <i>J. Allergy Clin. Immunol.</i> 110: 797-804, 2002.</p> <p>*Kowalski, et al., "Mechanisms of Specific Immunotherapy of Allergic Diseases", <i>Allergy</i>, 53: 485-492, 1998.</p> <p>*Ledesman, et al., "Cloning, Expression and Characterization of a Novel Four EF-Hand Ca^{2+} - Binding Protein from Olive Pollen with Allergenic Activity", <i>FEBS Letter</i>, 466: 192-196, 2000.</p> <p>*Lee, et al., "Oral Administration of IL-12 Suppresses Anaphylactic Reactions in a Murine Model of Peanut Hypersensitivity", <i>Clinical Immunology</i>, 101(2): 220-228, 2001.</p> <p>*Leung, et al., "Effect of Anti-IgE Therapy in Patients with Peanut Allergy", <i>N. Engl. J. Med.</i> 348: 986-993, 2003.</p> <p>*Li, et al., "A Murine Model of Peanut Anaphylaxis: T- and B-Cell Responses to a Major Peanut Allergen Mimic Human Responses", <i>J. Allergy Clin. Immunol.</i> 106: 150-158, 2000.</p> <p>*Li, et al., "Novel Approaches for the Treatment of Food Allergy", <i>Current Opinion in Allergy and Clinical Immunology</i>, 2: 273-278, 2002.</p> <p>*Li, et al., "Engineered Recombinant Peanut Protein and Heat-Killed Listeria Monocytogenes Coadministration Protects Against Peanut-Induced Anaphylaxis in a Murine Model", <i>The Journal of Immunology</i>, 170: 3289-3295, 2003.</p> <p>*Li, et al., "Strain-Dependent Induction of Allergic Sensitization Caused by Peanut Allergen DNA Immunization in Mice", <i>The Journal of Immunology</i>, 162: 3045-3052, 1999.</p> <p>*Lombardero, et al., "cDNA Sequence Analysis of the Main Olive Allergen, Ole e I", <i>Clinical and Experimental Allergy</i>, 24: 765-770, 1994.</p> <p>*Lopata, et al., "Characteristics of Hypersensitivity Reactions and Identification of a Unique 49 kd IgE-Binding Protein (Hal-m-1) in Abalone (<i>Haliotis Midae</i>)", <i>J. Allergy Clin. Immunol.</i> 100: 642-648, 1997.</p>			

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<p>*Moneo, et al., "Isolation and Characterization of a Major Allergen from the Fish Parasite <i>Anisakis simplex</i>", <i>J. Allergy Clin. Immunol.</i> 106: 177-182, 2000.</p>			
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<p>*Morafo, et al., "Genetic Susceptibility to Food Allergy is Linked to Differential T_H^2-T_H^1 Responses in C3H/HeJ and BALB/c Mice", <i>J. Allergy Clin. Immunol.</i> 111: 1122-1128, 2003.</p>			
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<p>*Oppenheimer, et al., "Treatment of Peanut Allergy with Rush Immunotherapy", <i>J. Allergy Clin. Immunol.</i> 90: 256-262, 1992.</p>			
<p>*Paddock, et al., "Identification, Cloning, and Recombinant Expression of Procalin, a Major Triatomine Allergen", <i>The Journal of Immunology</i>, 167: 2694-2699, 2001.</p>			
<p>*Palosuo, et al., "Wheat ω-5 Gliadin is a Major Allergen in Children with Immediate Allergy to Ingested Wheat", <i>J. Allergy Clin. Immunol.</i> 108: 634-638, 2001.</p>			

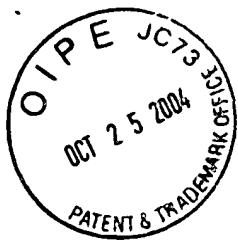
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<p>*Pastorello, et al., "The Major Allergen of Sesame Seeds (<i>Sesamum Indicum</i>) is a 2S Albumin", <i>Journal of Chromatography B</i>, 756: 85-93, 2001.</p>			
<p>*Pastorello, et al., "Allergenic Cross-Reactivity Among Peach, Apricot, Plum, and Cherry in Patients with Oral Allergy Syndrome: An In Vivo and in Vitro Study", <i>J. Allergy Clin. Immunol.</i> 94: 699-707, 1994.</p>			
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<p>*Romagnani, et al., "The Role of Lymphocytes in Allergic Disease", <i>J. Allergy Clin. Immunol.</i> 105: 399-408, 2000.</p>			
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